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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,057	06/26/2001	Roberto Alcantara Martins Zuchetti	32286R006	6856

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SMITH, GAMBRELL & RUSSELL, LLP  
1850 M STREET, N.W., SUITE 800  
WASHINGTON, DC 20036

EXAMINER

OSTRUP, CLINTON T

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 07/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/786,057

Applicant(s)

ZUCCHETTI ET AL.

Examiner

Clinton Ostrup

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 April 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☒ Claim(s) 17-18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

Claims 1-18 are pending in this application.

### **Response to Applicant's Arguments/Amendment**

Applicant's arguments and amendment filed April 24, 2002, Paper No. 9, to the rejection of claim 5 under 35 U.S.C. 112, second paragraph have been fully considered, however, the arguments and the amendment have not made the rejection moot. Therefore, the said rejection has been MAINTAINED for the reasons set forth in the Office Action mailed December 5, 2001 and those found below.

Applicant argues that the specification lists examples of "skin structures", "micronutrients of the skin", and "sensorial agents". The examiner respectfully disagrees, as the claims should "stand alone." The specification gives two examples of "skin structures", one example of "skin micronutrients", and two examples of "sensorial agents" and although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

Applicant's arguments and amendment filed April 24, 2002, Paper No. 9, to the rejection of claims 1-6 under 35 U.S.C. 102(a,e) as being anticipated by Rinaldi et al., 5,891,470 have been fully considered and deemed persuasive, Therefore, the said rejection has been withdrawn.

### ***Claim Objections***

Claims 17 and 18 are objected to because of the following informalities: These claims contain abbreviations without first clearly defining said abbreviations. Although

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the use of abbreviations is permissible, they should be preceded by the term they intend to abbreviate. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 5-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is vague and indefinite because it is unclear what is meant by the following terms: skin structures, micronutrients of the skin, and sensorial agents. These terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "associated to" in claim 15 is a relative term which renders the claim indefinite. The term "associated to" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. This phrase renders the claim indefinite because it is unclear what is meant by "associated to". Does this phrase mean polymerized to, touching, in the same composition, or does it have some other meaning?

Any remaining claims are rejected as depending on indefinite base claims.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rinaldi et al **5,891,470** and further in view of Huc et al., 5,395,620.

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Rinaldi et al teach soft gel formulations comprising retinol-impregnated microparticles and ascorbic acid which may be present as ascorbic acid-impregnated microparticles and/or within the emulsion. See: col. 1, line 5 – col. 2, line 10 and abstract. The reference teaches how to make the microparticles and also describes how the retinol will frequently will be a commercial blend containing antioxidants such as, vitamin E. See: col. 3, line 39 – col. 4, line 56. The reference describes an emulsion formulation comprising amounts of retinol, ascorbic acid, and antioxidants in amounts which overlap those of instant claims 2-6. See: col. 6, line 29 – col. 7, line 41.

Rinaldi et al specifically teach combining ascorbic acid-impregnated particles and retinol-impregnated particles comprising a retinol blend, tocopheryl acetate, ascorbic acid, disodium EDTA, and propyl gallate, together to obtain a softgel capsule. See: col. 7, lines 42 – col. 9, line 30. Renaldi et al., teach EDTA and cyclomethicone in the softgel capsules comprising microcapsules of retinol and microcapsules of ascorbic acid, thus teaching the specific ingredients of instant claims 5, 13, and 17. See: Example 3. The reference teaches BHT as a useful oil-soluble antioxidant and teaches glycerin in the first phase of the emulsion. See: col. 6, line 59 – col. 7, line 9.

The primary reference teaches compositions comprising microcapsules comprising Vitamin A, Vitamin C, and Vitamin E is a softgel capsule with microcapsules comprising Vitamin C, however, the reference does not specifically teach the microcapsules as being biologically active as claimed instantly in claim 1-18 or the specific ingredients of instant claims 8, 9, 12, 14, and 15-16.

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Huc et al., 5,395,620 teaches biodegradable microcapsules that are particularly useful for cosmetics because they improve the bioavailability and protection of the active principle. The secondary reference specifically teaches the microencapsulation of hydrophilic compounds such as, Vitamin C, and hydrophobic compounds such as, several types of oils. The secondary reference teaches problems associated with microcapsules made from synthetic polymers and describes the benefits associated with biodegradable polymers. See: col. 1, lines 10-39; col.2, line 38 – col.3, line 8; Examples 1-7, and abstract.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the microencapsulated compositions of Rinaldi et al., by using a biodegradable microcapsules as taught Rinaldi et al., because of the expectation of obtaining a composition comprising microencapsulated active ingredients which are not toxic and improve bioavailability and protect the microencapsulated active principle. It would have also be obvious to substitute known ingredients which are being used for their art recognized purpose such as, skin structures, micronutrients, emollients, sun protection factors, emulsifiers, and thickeners for another, because of the reasonable expectation of obtaining compositions with similar chemical properties.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


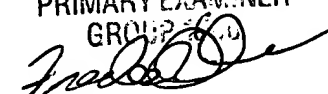
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on M-F (8:30am-5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Clinton Ostrup  
Examiner  
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FREDERICK KRASS  
PRIMARY EXAMINER  
GROUP 60  




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